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EXAMINER	
FORMAN, BETTY J	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,223	HICKEY, PATRICK COLIN	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *22,23 and 33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group 1 (Claims 1-32) and the first species (Claims 14-21) in the reply filed on 26 August 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 22-23 and 33-38 are withdrawn.

Claims 1-21 and 24-32 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28 and 29 are each indefinite for the recitation "(in use)" because it is unclear whether a recitation within parenthesis further defines the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 8-10, 24, 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Handique et al (U.S. Patent No. 7,010,391, published 3 October 2002).

Regarding Claim 1, Handique et al disclose a biochip comprising a substrate defining a plurality of fluid holding areas (Fig. 1, Column 9, lines 25-51) comprising fluid separating means (actuator) for to prevent mixing of reagents in the holding areas until application of pressure (Column 2, line 36-Column 4, line 4). Handique et al further disclose a first holding area comprising an inactive substance and a second holding area comprising an activating substance wherein the separating means separates the first and second holding areas (i.e. reactants Column 9, lines 25-Column 10, line 20).

Regarding Claim 2, Handique et al disclose the biochip further comprising means for applying pressure to the fluid (Column 14, lines 40-65).

Regarding Claim 3, Handique et al disclose the biochip wherein the means for applying pressure comprises an expandable element (Column 14, line 64-Column 15, line 2).

Regarding Claims 8-10, Handique et al disclose the biochip wherein the separation means comprises a fluid when melted (e.g. wax or solder, Column 37, lines 13-22).

Regarding Claim 24, Handique et al disclose the biochip further comprising a cover comprising one or more perforations (i.e. ports, Column 40, lines 56-67 and Fig. 8 and 10B).

Regarding Claim 27, Handique et al disclose the biochip wherein the cover comprises a puncturable membrane e.g. rubber (Column 40, lines 61-63).

Regarding Claim 28, Handique et al disclose the biochip wherein the lower surface comprises optically transparent material (Fig. 11, Column 38, line 42-Column 39, line 23).

Regarding Claim 29, Handique et al disclose the biochip wherein the lower surface comprises glass (Column 43, lines 60-65).

Regarding Claim 30, Handique et al disclose the biochip wherein the substrate comprises silicon (Column 14, lines 24-36 and Column 43, lines 60-65).

6. Claims 1-9, 12-16, 18-19, 24, 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Quake et al (WO 02/40874, published 23 May 2002).

Regarding Claim 1, Quake et al disclose a biochip comprising a substrate defining a plurality of fluid holding areas (Fig. 19, #900, ¶ 206-213) comprising fluid separating means (valves, #944/934) for to prevent mixing of reagents in the holding areas until application of pressure (¶ 144). Quake et al further disclose a first holding area comprising an inactive substance (e.g. cells, ¶ 214) and a second holding area

comprising an activating substance (e.g. activating agents, ¶ 217) wherein the separating means separates the first and second holding areas (¶ 207-213).

Regarding Claim 2, Quake et al disclose the biochip further comprising means for applying pressure to the fluid (¶ 144).

Regarding Claim 3, Quake et al disclose the biochip wherein the means for applying pressure comprises an expandable element (¶ 147).

Regarding Claim 4, Quake et al disclose the biochip wherein the expandable element is expandable in response to heat (¶ 147). The instant claim defines a heat-expandable element and describes a process of applying the heat i.e. upon application of a light. The recitation of applying light is a recitation of intended use that does not further define the structure of the device because the claim does not define the device as having a light source. Therefore, Quake anticipates the heat-expandable element as claimed.

Regarding Claim 5, Quake et al disclose the biochip wherein the separation means comprises a membrane (¶ 239).

Regarding Claims 6-7, Quake et al disclose the biochip wherein the separation membrane comprises a polymer e.g. polyethylene (¶ 239-240).

Regarding Claim 8, Quake et al disclose the biochip wherein the separation means comprises a fluid (¶ 144, 147).

Regarding Claim 9, Quake et al disclose the biochip wherein the separation means comprises oil (¶ 144, 147).

Regarding Claim 12, Quake et al disclose the biochip of Claim 3 wherein the expandable element comprises a fluid (¶ 144, 147).

Regarding Claim 13, Quake et al disclose the biochip of Claim 3 wherein the expandable element comprises a oil (¶ 144, 147).

Regarding Claim 14, Quake et al disclose the biochip wherein one of the holding areas comprises a micro-organism and a second holding area comprises a fluid reactive with the micro-organism (pp 214-117).

Regarding Claim 15-16, Quake et al disclose the biochip wherein the micro-organism is bacteria or a fungus (¶ 214).

Regarding Claims 18-19, Quake et al disclose the biochip wherein the reactive fluid includes water e.g. culture medium (¶ 206).

Regarding Claim 24, Quake et al disclose the biochip further comprising a cover comprising one or more perforations (i.e. ports, Fig. 16B).

Regarding Claim 26, Quake et al disclose the biochip wherein the cover comprises a dialysis membrane (¶ 114, Fig. 17).

Regarding Claim 27, Quake et al disclose the biochip wherein the cover comprises a self-sealing membrane comprising silicon or rubber (¶ 241-253).

Regarding Claim 28, Quake et al disclose the biochip wherein the lower surface is transparent (¶ 140).

Regarding Claim 29, Quake et al disclose the biochip wherein the lower surface comprises glass (¶ 140).

Regarding Claim 30, Quake et al disclose the biochip wherein the substrate comprises silicon (¶ 129).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al (WO 02/40874, published 23 May 2002) in view of Handique et al (U.S. Patent No. 7,010,391, published 3 October 2002) and Dove (U.S. Patent No. 6,633,312, filed 24 April 2002).

Regarding Claims 10 and 11, Quake et al disclose a biochip comprising a substrate defining a plurality of fluid holding areas (Fig. 19, #900, ¶ 206-213) comprising fluid separating means (valves, #944/934) for to prevent mixing of reagents in the holding areas until application of pressure (¶ 144). Quake et al further disclose a first holding area comprising an inactive substance (e.g. cells, ¶ 214) and a second holding area comprising an activating substance (e.g. activating agents, ¶ 217) wherein the separating means separates the first and second holding areas (¶ 207-213).

Quake et al further disclose the biochip wherein the means for applying pressure comprises an expandable element (¶ 147) but is silent regarding a metal that is liquid at

room temperature. Handique et al teach a similar device wherein the expandable element is a metal (e.g. solder, Column 37, lines 13-22) but does not teach mercury as the expandable element. However, mercury was well known and routinely practices as liquid switch as taught by Dove who teaches that switches made of mercury function within a channel very quickly (i.e. milliseconds) to open and close channel structures (Column 2, lines 32-62). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the mercury switch of Dove to the channel actuator of Quake. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the benefit of rapid and response open/close impulse as taught by Dove.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al (WO 02/40874, published 23 May 2002).

Regarding Claim 17, Quake et al disclose a biochip comprising a substrate defining a plurality of fluid holding areas (Fig. 19, #900, ¶ 206-213) comprising fluid separating means (valves, #944/934) for to prevent mixing of reagents in the holding areas until application of pressure (¶ 144). Quake et al further disclose a first holding area comprising an inactive substance (e.g. cells, ¶ 214) and a second holding area comprising an activating substance (e.g. activating agents, ¶ 217) wherein the separating means separates the first and second holding areas (¶ 207-213).

Quake et al teach the biochip wherein the cells are fungal. Quake further teaches their cell-based assays uses bioengineered cells that luminesce or fluoresce in the presence of a selected analyte (¶ 331-345) which clearly suggests using any of the previously described cells, but the reference does not specifically teach bioengineered fungus. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to bioengineer the fungal cells of Quake with their reporter constructs. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on Quake's clear suggestion to do so. (¶ 333-336).

10. Claims 25 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al (WO 02/40874, published 23 May 2002) in view of Panofsky (U.S. Patent Applicant Publication No. 2001/0041343, filed 20 July 2001).

Regarding Claim 25, Quake et al teach the biochip wherein the cover comprises a membrane (Fig. 16) but does not teach filter paper membrane. However, covers comprising filter paper were well known in the art of cell assay as taught by Panofsky who teaches a similar device (Fig. 4-5) wherein a filter paper screens the cells based on size prior to the assay (¶ 22, 38) thereby providing size-selected cells onto the assay surface. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the size selection filters of Pankowsky to the device of Quake. One of ordinary skill in the art would have been motivated to do so

with a reasonable expectation of success and for the added benefit of pre-sorting the cells based on size as desired in the art (Pankowsky, ¶ 22, 38).

Regarding Claims 31-32, Quake et al teach the biochip wherein holding areas contain various reagents e.g. cell sample, growth media, fluorescent dyes, test compounds (¶ 214-217) but the reference does not teach fixatives or unknown test substance.

However, Pankowsky specifically teaches including a fixative as one of the solutions thereby preserving the cells for later of subsequent analysis (¶ 50-51). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the fixative solution of Pankowsky to the device of Quake. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the added benefit of preserving the cells for later of subsequent analysis as desired in the art as taught by Pankowsky (¶ 50-51). One of ordinary skill would have been further motivated to include an unknown test substance to the variety of solutions taught by Quake and/or Pankowsky so as to perform blind testing of the cells to thereby eliminate any experimenter bias.

11. Claims 20-21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al (WO 02/40874, published 23 May 2002) in view of Hillman et al (U.S. Patent No. 4,963,498, issued 16 October 1990).

Regarding Claims 20-21, Quake et al disclose a biochip comprising a substrate defining a plurality of fluid holding areas (Fig. 19, #900, ¶ 206-213) comprising fluid separating means (valves, #944/934) for to prevent mixing of reagents in the holding areas until application of pressure (¶ 144). Quake et al further disclose a first holding area comprising an inactive substance (e.g. cells, ¶ 214) and a second holding area comprising an activating substance (e.g. activating agents, ¶ 217) wherein the separating means separates the first and second holding areas (¶ 207-213).

Quake et al teaches the biochip comprises various cell types for performing various cell assays (¶ 124-125) but the reference does not teach cells on a hydratable filter paper or gel. However the claimed filters were well known and routinely practiced in the art at the time the instant invention was made as taught by Hillman et al.

Hillman et al teach a similar biochip comprising a plurality of holding areas (Fig. 2A) whereby fluids in the holding areas are prevented from premature mixing (e.g. Column 8, lines 56-58) and wherein the cells are placed on a hydratable matrix e.g. filter paper comprising reactants wherein the reaction occurs upon hydration of the filter (Example 6 and Column 16, lines 4-12). Hillman et al further teach that filter pre-prepared filter papers assures reproducibility of reagent addition (Column 16, lines 4-7). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the pre-prepared filters of Hillman to the biochip of Quake. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the added benefit of assay reproducibility as desired in the art (Hillman, Column 16, lines 4-7).

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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